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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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5644  
DATE MAILED 07 19 2003

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Please find below and or attached an Office communication concerning this application or proceeding

## Office Action Summary

Application No.

09/721,212

Applicant(s)

BOYLE, WILLIAM J.

Examiner

Ron Schwadron, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Involvement and Communication (PTO-804)
- 3) ☐ Statement of Inventor's Status (PTO-858) Paper No(s) \_\_\_\_\_

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1. Applicant's election of Group XI, claim 42 in Paper No. 3 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 3.

3. This application appears to intend to claim priority to parent applications 09/052,521, 08/842,842 and 08/880855. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

**The instant application has requested use of the sequence listing from parent application 09/052521. However, the submitted CRF from said application and the paper copy of the listing filed in the instant applications lack sequence listings for sequences disclosed in Figure 10. In addition, the description of said figure in page 7 of the specification refers to said sequences as SEQ. Ids 42 and**

reply.

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5. The abstract of the disclosure is objected to because it does not disclose the claimed method (eg. the method of claim 42). Correction is required. See MPEP § 608.01(b).

6. Applicant needs to update the status of US patent applications disclosed in the specification (pages 2,9,15).

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", *Vas-Cath, Inc. V. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed method.

The claimed method encompasses use of ODAR protein. The only ODAR protein disclosed in the specification is murine ODAR as per Figure 10. The claims encompass use of any mammalian ODAR including human ODAR. The claims encompass use of ODAR variants, mutants and alleles, yet there is no disclosure of such specific proteins in the specification. The claimed method encompasses use of osteoprotegerin binding

The claims encompass use of OPGBP variants, mutants and alleles, yet there is no disclosure of such specific proteins in the specification.

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Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See *Fiers*, 984 F.2d at 1171. 25

3. Regarding priority for the claimed method and the application of prior art, the claimed method is not disclosed in parent applications 08/842842 or 08/880855.

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Therefore, the filing date regarding the application of prior art is parent application 09/052521.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (US Patent 6,242,213) as evidenced by Dougall (US Patent Application Publication 2003/0021785).

Anderson teaches RANK and RANKL (see column 10). RANK is an ODAR (see specification page 61). RANKL is an OPGBP (see Dougall which discloses that RANKL is another name for an OPGBP, see column 1). Anderson discloses use of RANKL extracellular domain and RANK in a competitive immunoassay to detect inhibitors of RANK. Anderson does not teach use of RANKL per se in the aforementioned assay. A routineer would have used RANKL extracellular domain or cell bound intact RANKL in the instant assay because both bind RANK. While Anderson does not specifically teach that the assay uses a step wherein RANK/RANKL binding is measured in the absence of inhibitor, this step would be required in such an assay to determine whether binding was inhibited by the test compound. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Anderson discloses use of RANKL extracellular domain and RANK in a competitive immunoassay to detect inhibitors of RANK, while a routineer would have used RANKL extracellular domain or cell bound intact RANKL in the instant assay because both bind RANK and a step wherein RANK/RANKL binding is measured in the absence of inhibitor would be required in such an assay to determine whether binding

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12. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US Patent 6,017,729) as evidenced by Dougall (US Patent Application Publication 2003/0021785).

Anderson et al. teach RANK and RANKL (see column 10). RANK is an ODAR (see specification page 61). RANKL is an OPGBP (see Dougall which discloses that RANKL is another name for an OPGBP, see column 1). Anderson et al. disclose use of RANKL extracellular domain and RANK in a competitive immunoassay to detect inhibitors of RANK. Anderson et al. do not teach use of RANKL per se in the aforementioned assay. A routineer would have used RANKL extracellular domain or cell bound intact RANKL in the instant assay because both bind RANK. While Anderson et al. do not specifically teach that the assay uses a step wherein RANK/RANKL binding is measured in the absence of inhibitor, this step would be required in such an assay to determine whether binding was inhibited by the test compound. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Anderson et al. disclose use of RANKL extracellular domain and RANK in a competitive immunoassay to detect inhibitors of RANK, while a routineer would have used RANKL extracellular domain or cell bound intact RANKL in the instant assay because both bind RANK and a step wherein RANK/RANKL binding is measured in the absence of inhibitor would be required in such an assay to determine whether binding was inhibited by the test compound.

13. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (Nature) as evidenced by Dougall (US Patent Application Publication 2003/0021785) in view of Ni et al. (US Patent 5,981,220).

Anderson et al. teach RANK and RANKL (see abstract). RANK is an ODAR (see specification page 61). RANKL is an OPGBP (see Dougall which discloses that RANKL is another name for an OPGBP, see column 1). Anderson et al. do not disclose use of RANKL and RANK in a competitive immunoassay to detect inhibitors of RANK. Ni et al. teach competitive inhibition assays to detect antagonist of receptor ligand binding (see

required in such an assay to determine whether binding was inhibited by the test compound. It would have been prima facie obvious to one of ordinary skill in the art at

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the time the invention was made to have created the claimed invention because Anderson et al. disclose RANKL and RANK, whilst Ni et al. teach competitive inhibition assays to detect antagonist of receptor ligand binding. One of ordinary skill in the art would have been motivated to do the aforementioned because antagonists of any physiologically occurring receptor/ligand pair have art recognized uses (eg. to study the physiological function of the pertinent ligand/receptor or to affect receptor ligand interaction in vivo or in vitro).

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

GROUP 1600  
A 12

Ron Schwadron, Ph.D.

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING  
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: see enclosed communication

**Applicant Must Provide:**

- ☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Software Help, call (703) 308-4216

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE**